EXHIBIT 2

Questions for the Wholesale Distributors

Duty

1. In June of 2017, the DC Circuit Court of Appeals issued a ruling in the case Masters Pharm., Inc. v. DEA which outlines the duty imposed by federal law regarding suspicious orders:

> Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some "due diligence" and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement)

Masters Pharm., Inc. v. Drug Enf't Admin., 861 F.3d 206, 212–13 (D.C. Cir. 2017). *Do you agree this is the correct interpretation of the law?*

2. Distributors owe a duty to monitor suspicious orders of prescription opiates?

3. Distributors owe a duty to detect suspicious orders of prescription opiates?

4. Distributors owe a duty to investigate suspicious orders of prescription opiates?

5. Distributors owe a duty to refuse suspicious orders of prescription opiates?

6. Distributors owe a duty to report suspicious orders of prescription opiates?

7. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opiates for nonmedical purposes?

8. The foreseeable harm resulting from the diversion of prescription opiates for nonmedical purposes is abuse, addiction, morbidity and mortality.

9. The foreseeable harm resulting from the breach of these duties is the prescription opiate epidemic plaguing our country.

Suspicious Orders

"Suspicious orders" are defined as orders of an unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

1. How do you define an order of unusual size?

   -What is an order of usual size for the average pharmacy in West Virginia? Ohio? America?

   -Do you agree that an aggregate order of prescription opiates from a single pharmacy, in a single year, in excess of the population of the county is an order of unusual size?

   -According to the ARCOS data, more that 6.5 million prescription opiates were sold each year into Cabell County, West Virginia which has a population of 100,000. Do you agree that someone was necessarily filling orders of an unusual size?

   The McKesson lawyers advised a federal court in West Virginia as follows: "***Distributors …have no duty or ability to limit the amounts of opioids distributed based on the population of any locality***."[1] How can this possibly be true?

2. How do you define orders deviating substantially from a normal pattern?

   -Who determines the normal pattern?

   -What is a normal pattern?

   -What is the threshold to measure an increase in pills? 10%? 15%? 500%?

   -According to the ARCOS data, a distributor sold 500 prescription opiates in 2011 in Wyoming County, WV (population: **23,796**) and the following year sold 490,000 pills for an annual increase of 98,000%. Do you consider this a deviation from a normal pattern?

3. How do you define and orders of unusual frequency?

   -Who determines the usual frequency?

   -What is the normal frequency for the average pharmacy in West Virginia? America?

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[1] MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT McKESSON CORPORATION'S MOTION TO DISMISS COMPLAINT, *Cabell County Commission v. AmerisourceBergen Drug Corporation et al*, United States District Court for the Southern District of West Virginia (Case No. 3:17-cv-01665), p.5.

The purpose of the CSA

The main objectives of the CSA are to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. The CSA categorizes all controlled substances into five schedules. The drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and use of the substances listed therein. The CSA and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping. *Gonzales v. Raich*, 545 U.S. 1, 12–14 (2005) (internal citations omitted).

"Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *United States v. Moore*, 423 U.S. 122, 135 (1975).

1. Do you agree "*the main objectives of the CSA are to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances*"?

2. Do you accept that "*Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels*"?

3. To effectuate these goals, you understand that "*Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA*"?

4. Do you understand that the Congress "*closed*" the chain of distribution "*to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market*"? 1970 U.S.C.C.A.N. 4566, 4571-72.

5. If you don't do your job, prescription opiates get abused, used for nonmedical reasons and diverted into the blackmarket. Do you agree?

6. Filling suspicious orders "has a substantial and detrimental effect on the health and general welfare of the American people."

7. The "DEA regulations that have been in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them." *See* Brief for HDMA and NACDS, *4, *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, Exhibit 5.

HDMA amicus groups

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Masters Pharm., Inc. v. Drug Enf't Admin., 861 F.3d 206, 212–13 (D.C. Cir. 2017). The Healthcare Distribution Management Association and National Association of Chain Drug Stores submitted amicus briefs in this case. Did you consent to these amicus briefs?

2. The industry advised the DC Circuit Court of Appeals that the "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled. ***Those added obligations would significantly expand the "report-only" duty of distributors under the longstanding regulatory scheme and impose impractical obligations on distributors***." Do you support the position taken by your trade groups?

3. The industry advised the DC Circuit Court of Appeals that the "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications." Do you support the position taken by your trade groups?

4. The industry advised the DC Circuit Court of Appeals that "Nothing in [the federal regulations] requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious." Do you support the position taken by your trade groups?

5. The industry advised the DC Circuit Court of Appeals that "DEA's regulations [] sensibly impose [] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders." Is this the position you have taken leading up to the decision in the Masters case?

6. Does this in part explain why your company did not investigate and halt suspicious orders?

7. You simply did not believe it was your job?

Causation

1. The CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are 40x more likely to be addicted to heroin. *See* CDC Vital Signs Fact Sheet, *Today's Heroin Epidemic*, U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention (July 2015).

Do you agree that filling suspicious orders of prescriptions opiates is a direct and proximate cause of the heroin epidemic plaguing our country?

2. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions. *See* Nora D. Volkow, M.D., and A. Thomas McLellan, Ph.D., *Opioid Abuse in Chronic Pain*, NEW ENG. J.MED., 374:1253-63 (March 31, 2016)

3. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications." *See* Special Report, FDA Commissioner Robert M. Califf, M.D., *A Proactive Response to Prescription Opioid Abuse*, NEW ENGL. J. MED., 374;1480-85 (April 14, 2016)

4. The increased use of prescription painkillers for nonmedical reasons (without a prescription for the high they cause), along with growing sales, has contributed to a large number of overdoses and deaths. *See* Press Release, *Prescription painkiller overdoses at epidemic levels*, U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention (November 1, 2011)

5. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes." *See* Richard C. Dart, MD, et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, NEW ENGL. J.MED., 372:241-248 (January 15, 2015).

Overview

1. As a Wholesale Distributor of prescription opiates, do you agree that you owe a duty under federal law to monitor, detect, investigate, refuse and report suspicious orders? 21 U.S.C. § 823, 21 CFR 1301.74

2. Do you agree that the foreseeable harm of a breach of this duty is the diversion of prescription opiates for nonmedical purposes?

3. In other words, if you ship a suspicious order, it is likely that prescription opiates will be diverted into the illicit market. Agree?

4. Do you concur that filling suspicious orders is a direct and proximate ***cause*** of prescription opiate abuse, addiction, morbidity and mortality?

5. Do you agree the United States is in the midst of a prescription opiate epidemic?

6. Do you concur that filling suspicious orders is a direct and proximate ***cause*** of the prescription opiate epidemic plaguing our country?

7. Do you believe the prescription opiate epidemic is an immediate ***hazard to public health and safety***.

8. Do you believe the prescription opiate epidemic is a ***public nuisance.***